# PSNC Health Policy and Regulations Subcommittee Agenda

# for the meeting to be held on Tuesday 14th July 2015

# at Park Inn by Radisson Palace, Church Road, Southend-on-Sea, SS1 2AL

# starting at 11.30am

**Members:** Ian Cubbin (Chair), David Evans, Margaret MacRury, Prakash Patel, Janice Perkins.

## Apologies for absence

No apologies for absence have been received at the time of setting the agenda.

## Minutes of the previous meeting and matters arising

The minutes of the meeting held on 12th May 2015 were shared with the subcommittee and can be downloaded from PSNC's website.

## Agenda and Subcommittee Work

Below we set out progress and actions required on the proposed work plan areas for the year. The subcommittee is first asked to review the proposed work plan areas for the year. The subcommittee is then asked to consider the reports; to address any actions required; and comment on the proposed next steps.

| 1 | Seek the best possible resolution of prescription direction | Status |
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## Report:

### Poster campaign

NHS England circulated amended wording for the poster in early June for further comments, and has finalised the text. This will be taken through the NHS England Gateway process before publication. PSNC will print and distribute the poster to pharmacies with Community Pharmacy News (probably the August 2015 edition). We will promote the poster on the website and also ask LPCs to help ensure their contractors are aware of it. Any update will be given at the meeting.

NHS ENGLAND LOGO

*Your prescription; your choice*

You have the right to collect medicines that have been prescribed for you from any pharmacy you choose.
No-one, including GPs, pharmacists or letters you receive in the post, should influence your choice.
Please contact NHS England if someone is trying to influence your decision on which pharmacy you would like to use.
[NHS England complaints address/contact details]

A meeting took place between Dr David Geddes (Head of Primary Care Commissioning, NHS England), Steve Lutener and Sue Sharpe in mid-June and he proposes to alert GPs to the poster through the GP bulletin (NHS England does not have a paper based communication facility with GPs). NHS England will not be able to instruct GPs to print and display the posters, but will ask that they do so.

### Ongoing monitoring and support

The contractor update on prescription direction, including an update on PSNC's work and FAQs to help them to address any local issues, were published in May 2015.

At the meeting with Dr Geddes we identified nomination as a major enabler of direction of prescriptions. PCTs had a duty to pro-actively monitor but this did not happen, and NHS England does not appear to have the resource with the currently available information to reassure LPCs and contractors that it has the ability to pro-actively monitor and take action. It may be necessary for LPCs and contractors to alert NHS England local offices to possible instances of direction of prescriptions and the subcommittee is therefore asked to consider a paper on Nominations at **Appendix HPR 02/07/15** which may provide the tools to help identify suspicious data.

**Subcommittee Action:**

- The subcommittee is asked to consider the two questions posed in the attached paper.

**Next Steps:** Once NHS England has agreed the poster campaign, PSNC will print and distribute to each pharmacy.

| 2 | Secure changes to the regulatory framework governing provision of pharmaceutical services that support and protect the interests of contractors | Status |
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**For Decision**

**Consultation on market entry applications and timescales for determining Applications**

One of the work-streams agreed by the subcommittee is that in order to address the failures of some NHS England teams to consult the appropriate parties and to determine applications within the statutory timescales, PSNC should examine the regulatory framework which exists; identify any provisions which are causing difficulties, and develop proposals for amendment of the regulations that would solve the problems faced by the NHS England teams (some of which have limited experience). It was agreed that a paper would be brought to this meeting of the subcommittee.

The subcommittee is asked to consider the paper set out in **Appendix HPR 03/07/15**. The subcommittee is asked whether any further action is needed at this stage, in the circumstances where NHS England is making changes that could alleviate the problems.

**Right Hand Side of the Prescription**

One of the consequences of the rapidly increasing adoption of EPS is that PSNC needs to consider the use by some prescribers of the prescription token (i.e. the right hand side of a paper prescription) to pass on messages to patients.

Many contractors report that GPs overuse their ability to send messages to patients via the right hand side of the token and consequently non-routine information is difficult to spot. Over the last two years most GP practices have introduced 'patient facing services', i.e. the ability for patients to securely view part of the medical record, re-order prescriptions and book appointments online. This means that many regular patients can now interact electronically with their GP practice and this can include via secure email (which is possible via nhs.net email).

This development in the electronic relationship between the patient and GP practice raises the question as to why pharmacies should be passing on messages to patients via EPS prescription tokens, when practices could and arguably should be doing this directly.

The Department of Health has been asked whether there are any legal provisions requiring a pharmacist to pass information on to the patient (we do not believe there are), and if the response

confirms our understanding, there may be an opportunity to make a request to NHS England and HSCIC that all functionality within electronic prescribing systems that replicate the right hand side of the prescription be removed – on the grounds that there are no requirements on pharmacists to act as messengers.

**Subcommittee Action:**

- The subcommittee is asked to consider whether this should be the policy of PSNC, so that progress can be made when the Department of Health responds.

**Distance selling pharmacies – amendment of clinical governance provisions**

The subcommittee decided that it would take the opportunity to consider the clinical governance provisions within the terms of service and the related 'Approved Particulars' to determine whether these should be amended to ensure that a distance selling pharmacy, when complying with the terms of service, would not contravene the regulations that apply to the DSPs. A paper for consideration by the subcommittee is set out in **Appendix HPR 04/07/15**.

The proposal is only to consider the clinical governance framework – and the subcommittee will see that changes can be accommodated by amending only the Approved Particulars. As NHS England needs to amend the Approved Particulars, it would be timely to make proposals now.

**Subcommittee Action:**

- The subcommittee is asked to consider the paper set out in Appendix HPR 04/07/15 and to make proposals as appropriate.

Note: Another piece of work planned for the subcommittee is to consider the remainder of the terms of service, including deciding whether these should be amended for distance selling pharmacies, so that the practicalities can be recognised, and the terms of service aligned better to the services that can be provided from a DSP. That paper will be presented at a future meeting of the subcommittee – the current paper has been prioritised as NHS England is expected to make changes to the Approved Particulars in the near future).

**Guidance to Local Authorities on the benefits of involving LPCs**

We raised with the Department of Health the concern of LPCs that some local authorities are not engaging with them, even when considering the commissioning of pharmacies. The response was:

> The Health and Social Care Act 2012 gave local authorities (LAs) the leading role in improving their population's health and the Secretary of State the duties to protect the nation's health and reduce health inequalities. With this in mind local government is best placed to shape solutions that address local needs, tackle the causes of ill health and build healthier communities, driven by democratically accountable leadership and supported by national action. Accountability for delivery in the public health system is rightly at local level. LAs do not account for their public health function to Public Health England, the Secretary of State or Parliament. They are each answerable to their own electorate.
>
> The services commissioned by LAs from community pharmacies are not "pharmaceutical services" – it is only services which are commissioned under Section 126 & 127 of the NHS Act 2006 (as amended) which are "pharmaceutical services". Therefore it is our understanding that this means that Section 167 of the NHS Act 2006 (as amended) does not bite on services commissioned from a community pharmacy by a LA. It is for each LA to procure the services needed by its local population and to ensure that any such services are of the appropriate quality and provide value for money.

> I understand there is concern that the remuneration for services commissioned by LAs from community pharmacies may differ across the country and even within authority areas. However, this is not something that DH is able to influence. May I suggest that PSNC makes links with the Local Government Association (LGA) who may be able to suggest to LAs that it is good practice to liaise with LPCs when considering commissioning services from local pharmacies. It may also be worthwhile for individual LPCs to begin dialogue with their LAs who are the commissioners of these services.

We did not, in fact, make the point that there are different prices being offered in different areas – our request was:

> *Under the provisions in the NHS Act 2006 (section 167) a Local Pharmaceutical Committee (LPC) is recognised by the NHSCB and as a result, is required to be consulted by the NHSCB when specified matters concerning pharmacy contractors in their area are being considered. There is no similar obligation on local authorities to consult LPCs of which we are aware, other than in respect of the Pharmaceutical Needs Assessment.*
>
> *As Local Authorities receive NHS funding, and some of the services that they procure are NHS services, PSNC believes there should be an obligation similar to that applying to the NHSCB, requiring Local Authorities to consult LPCs where they are determining remuneration for NHS services which they may commission from pharmacies.*
>
> *This may require changes to legislation, and if so PSNC asks that the Department of Health considers this in due course. In the meantime, we believe it would be very helpful if the Department of Health issued guidance about the recognition by the NHS of LPCs, and the benefits of consulting them in matters relating to pharmacy contractors.*
>
> *If the Department of Health believes that there are already statutory duties to consult, we would be pleased to be informed. If there are no statutory provisions, we would be pleased to hear the Departments' views on consultation of LPCs by local authorities, and what steps can be taken to improve engagement.*

The Department makes the point that it cannot influence local authorities, and recommends that PSNC contacts the Local Government Association (LGA). We will write a letter to the LGA about this matter and this will also be a useful opportunity to engage with them to promote the recent Health Service Journal/Local Government Chronicle supplement. However, the purpose of LPCs raising concern with PSNC and the reason the matter was considered by HP&R subcommittee was the apparent lack of a statutory duty to consult the LPC on matters related to commissioning of NHS services. The subcommittee is asked what further action may be appropriate.

**Report:**

**Seven day access (New deal for general practice)**

Members of the subcommittee may have seen the speech on the new deal for general practice. Within the speech was the call to extend the seven day access to primary care that had been piloted as part of the Prime Minister's Challenge Fund. Attention was drawn to Brighton where GP practices are working with local pharmacies to create primary care clusters offering evening and weekend appointments with a GP or pharmacist, with the pharmacist having access to the GP records.

This is reported to the subcommittee because the current terms of service require 40 core contractual hours per week together with supplementary hours. There are no requirements for pharmacies to open at the weekends unless they have specified those hours during their applications (or if NHS

England directs a pharmacy to open). It is possible that there may be discussion about pharmacy opening hours as the seven day access project proceeds.

## Rebalancing

The PSNC response to the consultation on rebalancing is set out in **Appendix HPR 05/07/15**.

The Minutes of the May meeting of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board have been published. The Chairman recognised that the election may have an impact on progress. The Board was due to meet on 16th June 2015 and the Implementation Group is due to meet on 6th July 2015. Any updates will be given at the meeting.

## Inducements

Following the May 2015 meeting at which it was agreed that three proposals for amendment of the GMS and Pharmaceutical Services Regulations would be made, Steve Lutener attended an informal meeting with officials at the Department of Health to outline the work streams of the HP&R subcommittee, and to put them on notice of the matters likely to be raised over the coming months.

Subsequent to the meeting a formal request to consider amendments to the regulations has been made, to:

- include in the GMS regulations a provision prohibiting a GP or medical practice from seeking or accepting payment (including payments in kind) in return for recommending that a patient uses a particular pharmacy;
- amend the PhS regulations to prohibit the payment, including payment in kind, for medical practices circulating pharmacy promotional materials with their own communications with patients; and
- amend the PhS regulations to prohibit the payment, including payment in kind, for a mailing list obtained from a medical practice – whether the list is handed to the pharmacy or whether the mailing list is provided through a third party on behalf of the medical practice.

At the time of preparing the agenda no response had been received.

## Same or adjacent premises and pharmacy closures

The Department of Health was contacted about Regulation 31 and its impact on mergers and closures of pharmacies. An official responded to say that the current policy position is that Regulation 31 should apply to all applications and that the two decisions – withdrawal from the list at one site and relocation to another - are sequential and should not be combined as a single application. But the official also said that it may now be time to rethink that particular part of the policy – which will need to include seeking the views of NHS England. The office had written also to Dr David Geddes making the same points. Any progress will be reported at the meeting.

We also asked the Department of Health to consider giving advice to Local Authorities about the benefits of considering the reason for closure of a pharmacy when deciding whether to issue a supplementary statement.

The DH response was:

> *Turning to the issue of guidance to HWBs about whether they should issue a supplementary statement when a pharmacy closes. We agree that it is for the HWB to consider whether the closure of a pharmacy could have an impact on the provision of pharmaceutical services which would be relevant to the granting of applications. We have already provided information to support local authority HWBs in a practical way in understanding and implementing the requirements of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 see link below -*

*https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/197634/Pharmaceutical_Needs_Assessment_Information_Pack.pdf*

The guidance issued in 2013 does include an example – a contractor with several outlets in the HWB area gives notice that it intends to close all or some of these outlets. The HWB may consider whether the making of a revised assessment is a proportionate response. Will the provision of services be continued for its population, i.e. are there alternative providers of services? Would closure of all or some of the outlets warrant a full-scale revision of the PNA or would that be disproportionate, taking into account all relevant circumstances? If the change in the availability of pharmaceutical services is likely to have an impact on the need for additional pharmaceutical services, the HWB may consider issuing a supplementary statement.

Clearly the Department of Health flags the need for the local authority to take a proportionate response, and this paragraph does provide something of a steer. It does not go far enough to explain to an organisation that has only recently become responsible for preparing PNAs, but it would be helpful to an LPC to aid discussions about the circumstances when a supplementary statement is a proportionate response and when it is not. The office will prepare a briefing for LPCs to use in discussions with their relevant local authorities.

**GPhC consultation on investigating committee meetings and outcomes guidance**

The General Pharmaceutical Council has consulted on its meetings and outcomes guidance for the Council's investigating committee. The consultation is open until 11th September 2015. It is not thought that this is a matter within PSNC's remit, but the subcommittee is informed in case there are alternative views. See http://www.pharmacyregulation.org/icg.

**Making health and social care information accessible**

NHS England has published a summary of the outcome of its consultation on an 'accessible information standard' and has decided to introduce a standard that must be complied with by all organisations that provide NHS services, by 31st July 2016 (but some preparation is required before then. The standard will apply to pharmacies.

The 'Accessible Information Standard' directs and defines a specific, consistent approach to identifying, recording, flagging, sharing and meeting the information and communication support needs of patients, service users, carers and parents, where those needs relate to a disability, impairment or sensory loss.

The Standard applies to service providers across the NHS and adult social care system, and effective implementation will require such organisations to make changes to policy, procedure, human behaviour and, where applicable, electronic systems. Successful implementation is intended to lead to improved outcomes and experiences, and the provision of safer and more personalised care and services to those individuals who come within the Standard's scope.

It seeks to set the framework and provide clear direction for a dramatic improvement in the ability of the NHS and adult social care system to meet the information and communication support needs of disabled people. Applicable organisations have a legal duty to follow this standard.

Significant support to enable effective, efficient implementation is to be made available to organisations, as outlined in the Implementation Plan, along with detailed Implementation Guidance. The Standard allows for flexibility in implementation approaches, subject to successful achievement of the stated requirements and outcomes.

For more information, see http://www.england.nhs.uk/ourwork/patients/accessibleinfo-2/

The office will prepare briefing materials for pharmacy contractors.

## Co-commissioning of primary care

The NHS England policy team on co-commissioning met Sue Sharpe, Alastair Buxton and Steve Lutener in June to hear directly the concerns we have about co-commissioning, and particularly about how pharmacy needs to be satisfied that there are effective powers and sanctions to address the conflicts of interests for GPs when involved in commissioning decisions affecting pharmacy.

There was a good discussion and it was clear that there was a gap in the awareness of the primary care relationships and how conflicts of interest arise. We raised recent examples of conflicts of interest and followed up, at their request, with a paper for presentation to their Board.

## Greater Manchester

It was reported to the subcommittee at the May 2015 meeting that Pharmacy Voice was to invite PSNC to discuss developments in commissioning. An invitation is still awaited.

Since the last meeting Community Pharmacy Greater Manchester has been discussing with the office the possibility of incorporating a local provider company, and how the PSNC's template Articles of Association might be revised to meet the challenges of establishing a provider company across seven LPC areas.

## Psychoactive Substances Bill

The Department of Health has formally notified PSNC of the above Bill currently in the House of Lords. This Bill will, if passed, render all products which can be used for its psycho-activity to be prohibited unless exempted (at present the listing is the other way around – products are legal unless listed (i.e. the so-called 'legal highs'). It is thought that this Bill will have no relevance to NHS pharmaceutical services, but is brought to the attention of the subcommittee to consider whether developments should be tracked.

## General Pharmaceutical Council - Fees

PSNC was consulted about proposed increases in the fees for pharmacy premises and for pharmacists and technicians. Our response opposed any increase in these difficult times.

The GPhC nevertheless increased the fees as proposed, and its Chief Executive Duncan Rudkin said the following when announcing the outcome of the consultation:

> *I wanted to write to let you know that our council has today decided to increase registration renewal fees for all of our registrants from 15 October 2015.*
>
> *The annual renewal fee for pharmacists will increase by £10, from £240 to £250. The annual renewal fee for pharmacy technicians will also increase by £10, from £108 to £118 and the annual renewal for pharmacy premises will increase by £20, from £221 to £241.*
>
> *I would like to thank you for responding to our consultation proposing this increase in fees; we had over 1,000 responses in total and you can read a report from the consultation here.*
>
> *Our council carefully considered the concerns raised by respondents to the consultation about this increase in fees as well as the overall economic context, but decided we needed to increase fees to meet the growing costs of regulation caused by a number of factors, including a rising number of complaints.*
>
> *We fully understand that the news of this increase may be unwelcome to our registrants but after three years where fees have either been kept at the same levels or reduced it has now*

*been necessary to increase fees. Even after the increase, fees for pharmacists and pharmacy technicians in 2016 will still be lower than those charged in 2011.*

*We have also looked for ways that we can reduce administration fees for those wanting to use direct debits to pay their renewal fee. A number of respondents to the consultation raised concerns in relation to the £15 administration fee that we have charged for setting up a quarterly direct debit. In response to this feedback, our council has approved removing this fee. This means people can now spread the cost of paying their fees over the year without incurring an extra fee.*

*Lastly, I just wanted to reaffirm our commitment to avoiding significant fluctuations in fee levels in future years for our registrants and to driving down our operating costs and achieving further operational efficiencies. We will continue to share information with you about how we are working to reduce our costs and how we are using registrants' fees to achieve our aims of protecting patients and improving pharmacy practice.*

## Secretary of State plans for publication of medicines prices

On 1st July 2015 the Secretary of State spoke at the LGA Conference on the need for people to take more responsibility for their own health care. As part of that he set out specific plans to publish indicative medicines costs to the NHS on the packs of all medicines costing more than £20 alongside a statement 'funded by the UK taxpayer'. The intention of this is to reduce waste but also improve patient care by improving adherence, and the Government hopes to begin implementation next year.

Clearly there will be implications for community pharmacy as this may impact on workload and change the conversations that patients wish to have in pharmacies. We will engage with the Department on this as soon as possible to ensure that all concerns are taken into account and that the impact on the sector is minimised. In the first instance we have published a public response to the announcement stressing how difficult any price printing scheme would be to implement. We also highlighted the role that pharmacy teams can play in helping people to take responsibility for their health by staying healthy, getting the most out of their medicines, and using pharmacy rather than urgent care services.

We are yet to receive formal communication on this policy from the Department but will update the subcommittee as soon as we know more.

## Fraudulent NHS Prescription exemption claims checking

There have been no further developments since the last meeting.

## Boxing Day

PSNC suggested to NHS England that LPCs could work with contractors and NHS England local offices, to secure opening by adequate numbers of pharmacies on 26th and 28th December 2015.

In late June 2015, NHS England contacted the office to say that the NHS England Primary Care Delivery Oversight Group had decided to issue a statement about 26th December stating that it considers community pharmacy to be an important part of its system resilience and that it will be asking all primary care contractors whose contracted hours include Saturdays to open their normal hours on 26th December 2015. Local arrangements will be put in place to ensure adequate pharmaceutical services are available on the Boxing Day Bank Holiday on 28th December 2015.

This means that it is unlikely that any NHS England local offices will exercise discretion to allow a pharmacy to change its core hours on 26th December in return for offering to open on the bank holiday 28th December. The removal of the discretion may lead to many pharmacies being compelled to open on 26th December which may reduce goodwill about opening on 28th December.

Whilst the office will assist LPCs and contractors who are contacted about opening on 28th December especially where due process has not been followed when NHS England issue directions, the pharmacy network will need to ensure that patients have adequate access to pharmaceutical services on both 26th and 28th December.

A notice has been placed on the website and in Community Pharmacy News to alert contractors and LPCs have been briefed about the consequences of this hard line being taken by NHS England.

**Pregabalin**

The Pfizer court case concerning the second use patent for pregabalin began at the end of June 2015 and was expected to last two weeks. Although the case should have concluded by the time of the subcommittee it is widely anticipated that the judgment will be reserved until a date later in the year.

**Information Governance Toolkit & Business Continuity Plan**

A meeting has now taken place between Alastair Buxton and Steve Lutener and representatives of NHS England and HSCIC.

The main area of discussion was the Business Continuity Plan template which PSNC has published on the website, but which has not yet been formally agreed by NHS England as providing a compliant framework sufficient to meet the requirements in the clinical governance requirements. The template was agreed to provide a good basis, although HSCIC suggested that it could be updated with some of the recent IG changes. HSCIC agreed to draft an appropriate section for PSNC to consider and Alastair Buxton agreed to refine the layout and contents in order to simplify use of the template by contractors.

It was also agreed that even though the template may eventually be accepted by NHS England as providing a compliant model, this would not prevent contractors from using their own business continuity plans.

The subcommittee will be informed when further progress is made – and there will then need to be negotiations on funding.

**Discretionary payments**

NHS England met with Steve Lutener in June 2015 to provide an update. It had discussed its position with the Department of Health and would shortly be taking its policy paper to its heads of primary care group for approval. We were told informally that there would be provision for very limited types of discretionary payments being approved. NHS England's position is likely to be that discretionary payments will be considered where the reason for not claiming within the Drug Tariff framework is not due to a fault on the part of the contractor.

Claims following contractors making mistakes in their FP34 submission claims are unlikely to be paid because NHS England does not want to encourage poor practice as well as holding the belief that as the Drug Tariff is the Secretary of State's prescribed arrangements for payment, it must not develop a routine system to bypass the requirements.

The policy paper when received will be referred to the subcommittee.

**Supply of controlled drugs to persons in police custody**

The subcommittee was informed at its May 2015 meeting about the working group that had considered the difficulties for patients in obtaining their prescribed controlled drugs when in police custody, especially those which are to be supervised.

The secretariat has taken the comments from the working group and a policy paper has been drafted, and has been circulated requesting comments by 17th July 2015. Once agreed, this will be published by Public Health England.

A copy of the draft is set out in **Appendix HPR 06/07/15** for information. A small number of points of correction have been sent on behalf of PSNC as shown on the draft.

| 3 | Develop alliances and collaborate with other trade organisations to lobby for desirable changes in legislation governing supply of pharmaceutical services | Status |
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**Report:**
The office remains in contact with Pharmacy Voice and NPA staff members on work to address the direction of prescriptions and to gather evidence where we believe prescriptions are being directed. The pharmacy organisations are also all working together to support the work of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board.

**Subcommittee Action:** None.

**Next Steps:** The office will continue to liaise with the other pharmacy organisations on the rebalancing and prescription direction work. As work to implement the Falsified Medicines Directive develops the office will continue to work closely with the other pharmacy organisations on the topic.

| 4 | Work with DH, other pharmacy organisations and MHRA to prepare for FMD implementation and ensure financial implications for pharmacy are captured and resolved | Status |
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**Report:**
Andrew Bonser (Walgreen Boots Alliance) gave a briefing to Sue Sharpe and Steve Lutener which included a presentation on 'the journey of a patient pack'. There was confirmation of many of the matters about which concerns had previously been discussed with the NPA, but one new piece of information was that there is likely to be a 10 day expiry date between the date of the authentication scan and the date beyond which the item cannot be put back into stock. This could have a massive impact on the processes for pharmacies (c.f. expiry of EPS prescriptions at 180 days, which is causing pharmacies problems).

As a result of the meeting Steve Lutener has also been invited to attend a Walgreen Boots Alliance stakeholder day on 17th July to visit a wholesaler and pharmacy, to examine the issues that apply in both types of business, and how these may be addressed. A report will be provided to the next meeting of the subcommittee.

Steve Lutener has received briefings from Adrian Price on behalf of PV and from Raj Patel and Gareth Jones representing NPA. There is a hiatus at present because all stakeholders are awaiting sight of the Delegated Acts (expected in the Autumn). Adrian has offered to act as liaison.

**Subcommittee Action:** None.

**Next Steps:** Report at the next meeting.

| 5 | Develop stakeholder understanding of community pharmacy's knowledge, skills and behaviours (professionalism) and their core values, including finances, the pharmaceuticals market, pharmacy procurement and distribution | Status |
|---|---|---|

**Report:**

**ESPLPS**

The subcommittee was concerned at its last meeting about the failure to complete the contracting of the former ESPLPS pharmacies using LPS contracts before the expiry of the ESPLPS contracts at the end of March 2015. There was concern that some pharmacies would be left without support by NHS England.

At the request of the subcommittee the office carried out a survey, contacting all the ESPLPS pharmacies to determine what stage of negotiations they were at, and to gain examples of irrational or unlawful behaviour by NHS England local offices if these would be sufficient to support a legal challenge.

In June, a Parliamentary Question (2508) was asked:

> **Question:** To ask the Secretary of State for Health, what steps he has taken to provide financial assistance to pharmacies that qualified for payments under the Essential Small Pharmacies Local Pharmaceutical Services Scheme; and if he will make a statement. (2508)
> Tabled on: 15 June 2015
>
> **Answer: Alistair Burt**: NHS England has been working with all essential small pharmacy local pharmaceutical services contractors. 82 of those on the scheme as at 31 March 2015 have returned to the pharmaceutical list, of which 48 contractors are in discussion with regional teams about proposals for continuing to provide pharmaceutical services under a local contract. 20 contractors are now providing services under such a contract. No community pharmacy has closed as a result of the ending of the scheme.

The data provided in the PQ was consistent with the information we had obtained in our survey.

During the last week in June 2015 when the Schedules of Payments were issued, three contractors contacted PSNC. All were concerned about the drop in income that was about to take place. Whilst two of the contractors were still in negotiations and had no interim funding arrangements in place, one had agreed and signed an LPS contract that should have provided support.

Steve Lutener immediately raised this matter with Dr David Geddes, and by 3rd July 2015 the contractor with the LPS had been paid and an apology given and accepted. The other two contractors are being contacted by the NHS England offices with an explanation.

The lack of consistency in providing short term interim funding to cover the delays whilst the public engagement exercises are carried out for some contractors but not others means that the payments at the end of June were devastating (and for some – unexpected) for some contractors.

The subcommittee will be updated at the meeting if there are any significant developments.

**Subcommittee Action:** The subcommittee is asked whether there is any further action it wishes to take.

**Next Steps:** A further update will be provided at the next meeting.

## Post-election lobbying and resources

We have now had confirmation of our fringe event at the Conservative Party conference which will be held on Monday 5th October at 12:45pm. We have invited Alistair Burt MP (the pharmacy minister) to chair this and Kevin Barron MP (chair of the All-Party Pharmacy Group) to chair the event at the Labour Party conference.

The title of the events will be 'Winter Health Pressures: how can we get the NHS ready?' We have agreed on a format with our partners the BAPW and DDA and are now all working on presentations and communications materials. Our priorities are to highlight the roles that pharmacy plays in reducing pressure on urgent care and GP services and improving public health.

Working with Pharmacy Voice we have refreshed the pharmacy manifesto website and provided joint resources to help LPCs to engage with politicians locally. We have agreed to share intelligence on pharmacy MP visits and will continue to support LPCs with these. We will also work with Pharmacy Voice on engagement with MPs following the summer recess and to build up to the party conferences work. We had hoped to be able to work with the RPS on some of the resources as well but unfortunately they have not so far been able to agree to co-badge any of the materials; we will however continue to try to include them in this work.

**Subcommittee Action:** The subcommittee is asked if there is any further action that should be taken.

**Next Steps:** As above, we will continue to work with PV and the RPS on post-election engagement and to prepare for our own fringe events.

## All-Party Pharmacy Group

Kevin Barron MP has agreed to continue as Chair of the All-Party Pharmacy Group and Luther Pendragon are working with him to reconstitute the group and to finalise a plan for its activity. A draft version of this plan is set out in **Confidential Appendix HPR 07/07/15**

The discussions on our ongoing support for the group became complicated as PV sought to reduce their contribution with immediate effect from May 2015. We have agreed that to give time to complete the review of future options and to get any new arrangement in place, pharmacy organisations will continue with their current level of contributions until the end of this year. All pharmacy organisations are working to develop possible future options for the Secretariat and this process will include an invitation to public affairs organisations to bid for the work. We expect the tender process to begin later in the summer so that a decision can be made in good time ready to take forward agreed arrangements in January 2016.

**Subcommittee Action:** None.

**Next Steps:** As above, we will continue to work with PV and the RPS to help the APPG to deliver its work plan and to agree our arrangements for support for the APPG from January 2016 onwards.

## Other stakeholder activities

The Health Service Journal/Local Government Chronicle supplement on community pharmacy services has now been published and copies will be available for Committee members at the meeting. The supplement links to a commissioner section of our website which includes services information relevant to commissioners (including the service prospectuses as covered in the LIS agenda). LPCs have now been sent a number of copies of the supplement for use in conversations with their local commissioners. In a survey sent before LPCs had received their copies more than 30% said they had already found the supplement useful and a further 55% said they hoped it would be useful in the future (the remaining respondents were not aware of the supplement). We have received positive

feedback from some LPCs and we will pull all this together as well as assessing impact more formally later in the summer once we and LPCs have had more opportunity to use the supplement.

Gary Warner and Liz Colling attended the HSJ integration summit in June (at which attendees received a copy of the supplement) to help ensure that pharmacy's role was recognised and discussed at the event. They reported that all copies of the supplement were picked up by delegates and that many had commented to them that they felt they ought to be using pharmacy more. At the gala dinner they hosted a table including directors of commissioning and public health, a chair of a health and wellbeing board and the President of the Association of Directors of Public Health.

Following discussions with Pharmacy Voice we have decided not to exhibit at the NHS Expo and the National Children and Adult Services Conference this year due to cost and resource constraints.

**Subcommittee Action:** The subcommittee is asked if there is any further action that should be taken.

**Next Steps:**

- We will continue to update the commissioner section of the website and to use our new emails to commissioners to promote the content on it;
- Feedback on the supplement has been positive but we will be assessing this formally over the summer, looking at the popularity of the webpage and surveying LPCs. We will also make use of the HSJ supplement at the party conferences and at the RCGP Annual Conference in the autumn, both of which we will be finalising preparations for in the next few weeks.

| 6 | Pursue action against the current practice of 'switching' as advised by Counsel | Status |
|---|---|---|

**Report:**
A **confidential** update will be given at the meeting.

| 7 | Examine opportunities for a national provider company, implementing if agreed | Status |
|---|---|---|

**Report:**
The task and finish group formed by the four pharmacy bodies (PSNC, NPA, CCA and AIMp) met to discuss the framework for a national provider company.

Further discussions have been held with the NPA, and it has been confirmed that the NPA has agreed a budget of £50,000 towards meeting 50% of the costs of a National Provider company. The LPC and Implementation and Support Subcommittee and Resource Development & Finance Subcommittee will be considering further the support and any required funding that should be provided by PSNC.

Instructions for lawyers to draft Articles of Association have been prepared.

A paper is included in the agenda of LPC and Implementation Support Subcommittee.

**Subcommittee Action:** The subcommittee is asked to consider the papers in LISS and RD&F subcommittees

**Next Steps:** Instructions to lawyers.

## Any other business

**Appendix HPR 02/07/15**

## Nomination of pharmacies

Since pharmacy dispensing data has been published, many people have been analysing the data to determine whether direction of prescriptions may be taking place, so that complaints can be made to NHS England for investigation.

One LPC has alerted the office to the fact that one contractor that operates a distance selling pharmacy increased the number of prescriptions it dispensed in March by 13,800. The figures on their own do not provide any evidence of direction of prescriptions, but in examples of this kind, the NHS should have in place a mechanism to assess whether this is direction of prescriptions by a GP (or practice) or whether nominations have been set without patient consent.

In 2013, HSCIC asked PSNC whether we were content to publish specific 'nomination per pharmacy' information. We opposed pharmacy specific information being published on the grounds of commercial sensitivity, but accepted some banded information being published.

As prescription volume is now readily available for each pharmacy it is questionable whether the opposition remains justified – and indeed whether publication would allow further scrutiny and analysis to help detect possible prescription direction / inappropriate setting of nomination.

Detailed reports are not available as a matter of routine so NHS England local offices must request a bespoke report if they wish to investigate allegations of inappropriate setting of nomination. LPCs have also asked for reports, but it is reported to take weeks to obtain a response.

It may be possible to encourage HSCIC / NHSBSA to publish data on a monthly basis, for example:

> Name / address of pharmacy;
>
> How many nominations have been set (or reset) for that pharmacy that month;
>
> How many nominations have been removed for that pharmacy (whether by de-nominating, or through a subsequent nomination of an alternative dispenser);
>
> The number of nominations set for that pharmacy - at that pharmacy; or by any (named GP practice); or by any named pharmacy.

Similarly there should be a data set for each GP practice reporting the number of nominations set / modified / removed for each named pharmacy.

The NHS England local office should also be able to drill into the data to see the Smartcard that was used when setting the nominations and the time at which each nomination change was made so that there can be forensic examination if complaints are made or monitoring data raises suspicion that the nominations may have been set without patient consent.

**The subcommittee is asked whether HSCIC should be approached with a view to making nomination reports available in the same way that prescription data is published.**

In addition to providing monitoring tools for interested contractors / LPCs and NHS England to use, the subcommittee is also asked to consider whether an approach should be made to the Department of Health / NHS England to introduce a simple mechanism for patients who have had their nomination 'switched' without their consent (in a similar way to that used in the energy industry). See

https://www.citizensadvice.org.uk/consumer/energy-supply/problems-switching-energy-suppliers/you-ve-been-switched-to-a-new-gas-or-electricity-supplier-without-your-consent/

Whist it is easier for a patient to switch their nomination back to their preferred pharmacy, compared with consumers trying to unravel gas and electricity switches, this could bolster the NHS England poster campaign.

**The subcommittee is asked whether DH / NHS England should be approached with a view to setting up a similar mechanism for patients to reset their nominations where these have been 'erroneously' set.**

**Appendix HPR 03/07/15**

## Consultation on market entry applications and timescales for determining applications

One of the subcommittee work-streams is that in order to address the failures of some NHS England teams to consult the appropriate parties and to determine applications within the statutory timescales, PSNC should examine the regulatory framework which exists; identify any provisions which are causing the difficulties, and to develop proposals for amendment of the regulations that would solve the problems faced by the NHS England teams (some of which have limited experience). It was agreed that a paper would be brought to this meeting of the subcommittee.

Examples of the problems include a case where a decision was not communicated for several weeks after the decision was made because the NHS England office concerned did not have anyone able to prepare the letter to the applicant; and several cases where the decision as to parties for consultation have been based solely on distance from the application site.

NHS England has recognised that there are benefits in streamlining the processing of applications, and whilst it has not taken the decision to centralise the decision making process, the Primary Care Support Service may be involved in some aspects of processing market entry applications.

NHS England commissioned DAC Beechcroft (a firm of solicitors that advise NHS England on many of the market entry appeals) to review its guidance. As part of that review process solicitors from DAC Beechcroft visited PSNC's offices to discuss the guidance.

They had concluded that the decision about who the interested parties to be included in consultation should be informed by a distance (for example 1km or 2km from the application site). Steve Lutener was able to provide them with a recent example where a body corporate in which local GPs have a financial interest had applied for a distance selling pharmacy just beyond that distance from the medical practice and using only distance as the criteria for selection would have missed the most significantly affected pharmacy. We emphasised that it may be necessary to lift the corporate veil to establish whether GPs are involved, and then identify from the now publicly available information which pharmacies are likely to be most affected.

The guidance has not yet been issued but should be issued shortly as the policies have a stated review date of June 2014.

In light of the contracting of much of the administrative process to Capita, it is more likely that there will be a consistent and compliant approach.

**Appendix HPR 05/07/15**

# Response to consultation on: Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999.

Thank you for consulting PSNC about the Department's proposals to amend the medicines legislation and Pharmacy regulation

PSNC welcomes the proposals to rebalance medicines legislation and pharmacy regulations, to remove the risk and fear of prosecution, when pharmacy staff make dispensing errors, where the error is not compounded by poor professional behaviour. This will encourage pharmacy contractors to increase the reporting of patient safety incidents – a long standing ambition which is currently thwarted by the risks associated with making self-incriminating reports.

The Committee's response to each of the questions is set out below:

**Question 1: Do you agree with our overall approach, i.e. to retain the criminal offence in section 64 and to provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions?**

PSNC understands that there is a desire to retain the criminal offence in section 64, so that those whose conduct can be described as criminal, may be prosecuted. But retaining section 64 and providing a defence does not remove the risk of prosecution for pharmacy staff who make a mistake – and this leaves pharmacists and others liable to prosecution unless they can rely on the defence. PSNC believes it would have been better for section 64 to be amended to remove the dispensing of prescriptions from the scope of the offence. This would remove the criminality of dispensing errors, and align the practice of pharmacy with other healthcare professions so that errors in the course of professional practice are not treated as matters of criminal conduct, but matters in which the professional regulator would have the responsibility for oversight. There is also a matter of perception – it is far better for one's conduct not to be a criminal act at all, than for it to be criminal but for the availability of a defence. Pharmacy has a professional regulator, the General Pharmaceutical Council (GPhC) and dispensing errors, whether they would satisfy the criteria for prosecution or not would fall well within the Council's powers to take action to protect the public. Retaining the section 64 offence is unnecessary.

Section 64 already contains wording relating to the dispensing of prescriptions, and it should have been possible to amend this section to include a clause excluding the dispensing of prescriptions or the dispensing against hospital orders from the offence.

Whilst the focus has been on providing a defence to possible offences under section 63 and 64, we feel it would be right also to flag that if there are defences available, the police and others may face pressure to consider prosecuting a pharmacist under other parts of the medicine legislation. In particular the sale or supply of a prescription only medicine other than under the authority of a prescription; the sale or supply of a product that is labelled incorrectly; or the sale or supply of a product without the correct patient information leaflet. Could we seek reassurance that there are already defences for such matters, or that there would be consideration of closing down these avenues as a fall-back where the defence to a s64 offence exists.

Having said all that, PSNC is concerned that the work to rebalance medicines legislation is not further delayed – the 'promise' to decriminalise dispensing errors remains outstanding and the bringing forward of the current proposals has been a long time in coming. If the Department of Health and the devolved governments are aligned on the current proposals and able to implement the proposal quickly, then PSNC will support the proposal as this may be the only option for timely progress, and we

do not want to lose the opportunity presented, to move in the right direction. But, if there is to be significant delay involving further detailed consideration of the proposals, then PSNC would ask that consideration be given to the above suggestion.

**Question 2: Do you agree that, once a defendant has done enough to show that the relevant pharmacy professional might have been acting in the course of his or her profession, the prosecution should have to show, beyond a reasonable doubt, that the pharmacy professional was not "acting in the course of his or her profession" in order to secure a conviction?**

The criteria which must be met for a person to rely on the defence are set out in a number of terms to be considered in the determination of whether the person is acting in the course of his or her profession. Paragraph 38(v) of the consultation requires the pharmacy to notify the error if it is discovered before the defendant is charged. It is not clear what this phrase means. Does this mean that every error, no matter how minor, must be notified, and if so, to whom? PSNC would support the need for pharmacists and their staff to be open and to act with integrity if an error is discovered, but it would not always be necessary for a pharmacist to notify the patient, for example, that a mistake has been made (for example the supply of a medicine which is one day out of date, discovered two months after the prescription had been dispensed where the course of treatment would have been completed). If on the other hand, the word notify is intended to describe a reporting obligation of the kind in the community pharmacy contractual framework in England, where a patient safety incident that did or could have caused harm must be reported to NHS England through the National Reporting and Learning Service (NRLS) then this would provide a more justifiable obligation.

Subject to satisfactorily clarifying what is meant in 38(v), PSNC would support the proposal for the prosecution to have the burden of proving, beyond reasonable doubt, that the defendant was not acting in the course of his or her profession.

**Question 3: Do you agree the two proposed illustrative grounds that the prosecution could rely on to establish that the pharmacy professional was not acting in the course of their profession, if they were proven beyond reasonable doubt?**

It is very helpful to illustrate what is meant by each of the terms used in the interpretation of acting in the course of his or her profession. The two illustrative examples are helpful, but further examples should be provided including for the other criteria because until there is established case law, the interpretation is going to be a grey area leaving pharmacists and pharmacy technicians unclear as to what is expected of them.

**Question 4: Do you agree that where a pharmacy professional does not follow procedures established for the pharmacy and an error takes place, this should not, on its own, constitute grounds for a decision in criminal proceedings that the pharmacy professional is not acting in the course of their profession?**

PSNC agrees that pharmacy registrants should be free to exercise their professional judgment and this may, on occasion, require the registrant to deviate from a standard operating procedure. In such cases the registrant should not be automatically deemed to be acting otherwise than in the course of their profession.

**Question 5: Do you agree that for the defence to apply, the sale or supply of the medicine must have been in pursuance of either a prescription or (in the case of sales) directions from an appropriate prescriber?**

The defence should apply not only to errors involving the dispensing of prescriptions and sales and supplies made against a Patient Group Direction, but also:

- Sales or supplies made where, exceptionally, a pharmacist independent prescriber issues the prescription and dispenses it himself (if this is not included in the defence, it could impede the development of independent prescribing).
- Sales of products made in accordance with a specification furnished by the purchaser;
- Sales of unlicensed products prepared to meet a special need of the patient (extemporaneously prepared medicines)

Under the community pharmacy contractual framework in England, pharmacies provide support for self-care, and may be called upon to recommend and sell medicinal products to allow the person requesting the medicine to look after themselves or another person that they represent.

In the case of the 'peppermint water' error, the substandard product was prepared in response to a prescription and under the proposals, the pharmacist may have a defence. But the defence needs also to be available if the pharmacist were to prepare extemporaneously such a medicinal product for over the counter sale.

**Question 6: In your view, should it be part of a defence where someone is charged with a dispensing error that if an appropriate person at the pharmacy knew about the problem before the defendant was charged, all reasonable attempts were made to contact the patient unless it was reasonably decided not to do so?**

As set out in response to question 2, there are occasions where notification of the patient or their representative would be unnecessary and may in some cases even be counter-productive if that caused undue alarm. As the possible defendants may include both the owner of the pharmacy business and the responsible pharmacist, there may be differences in notification. For example the responsible pharmacist may decide, exercising his professional judgement, that is it not necessary to notify the patient but fails to inform the owner that he has not notified the patient. If the owner is aware (through an internal incident report) and the owner has not notified the patient, the owner would inadvertently be unable to rely on the defence because he knew of the incident but did not notify (relying on the responsible pharmacist notification). The defence should still be available if the actions of the owner relying on the responsible pharmacist were reasonable in the circumstances.

PSNC would be content if the requirement was to be open and honest with patients who question whether an error has taken place, and for pharmacy registrants to be required to take timely remedial action, if they discover an error which could cause patient harm, and which may involve contacting the patient.

One of the reasons for rebalancing medicines legislation is to increase the reporting of patient safety incidents that have or could have caused harm, so that there can be national learning from incidents. It therefore follows that PSNC would support an obligation to report to NRLS any patient safety incidents that did or could have caused harm.

**Question 7: Do you agree that the unregistered staff involved in the sale or supply of a medicine (including, for example pharmacy assistants who hand over medicines that have been dispensed or van drivers who deliver medicines to patients) or the owner of the pharmacy where a dispensing error occurs should potentially be able to benefit from the new defences?**

Yes.

**Question 8: Do you agree that the defence should not apply in cases where unregistered staff involved in sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?**

Yes.

**Question 9: Do you agree with the overall approach to the new defence in section 67B in relation to the offence in section 63, i.e. to retain the criminal offence and provide a new defence subject to essentially the same conditions as will apply in relation to section 64? If you think different, additional or fewer conditions should apply, could you explain what, if any, conditions you think should apply.**

PSNC supports the proposal to provide for a defence to offences under section 63.

**Question 10: Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?**

PSNC supports a flexible system of regulation which is capable of keeping pace with developments in pharmacy practice, which might otherwise be stifled by delays in translating standards into statutory rules. However, as the GPhC is still a relatively new organisation, the pharmacy profession may not yet be comfortable with the GPhC being authorised to bring forward standards without external oversight. PSNC proposes that in its development of standards, the GPhC must be under a statutory duty to consult relevant stakeholders and to include with any proposals, its justification for change.

**Question 11: (for respondents in Northern Ireland): Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?**

N/A

**Question 12: Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?**

Not sure.

The proposal to treat failures to comply with premises standards as fitness to practise matters appears to provide for powers to suspend the registrant (the proprietor, partner or body corporate / superintendent) and for premises standards deficiencies to be taken as a matter of discipline as opposed to a matter for the registration committee.

The consultation paper does not appear to address the range of likely sanctions if an owner of a number of pharmacies fails to ensure compliance in one of their pharmacy premises. Under the provisions in the relevant part of the Medicines Act 1968, action could be taken in respect of single pharmacies that give rise to concerns as well as the whole business.

Treating failures to meet standards in one pharmacy premises of a pharmacy business as a fitness to practise issue may create a disproportionate outcome. Paragraph 117 for example seems to suggest that if one pharmacy is so far short of the required standards, that the matter would be taken as a fitness to practise case, with the pharmacy owner being found unfit to carry on the pharmacy business safely and effectively. If the owner is deemed unfit to carry on the pharmacy business safely and effectively would that lead to the removal of the owner and all the pharmacy premises?

We are not sure this is what is intended – The Medicines Act allowed action in respect of just one substandard pharmacy, leaving the rest of the pharmacy business intact. The current proposals may have the result of being an all or nothing matter with one substandard pharmacy causing the removal of the owner for being unfit, with the closure of all the pharmacies owned by the business.

PSNC does not support substandard pharmacy premises, but would not wish a pharmacy owner to be considered unfit if one (only) pharmacy premises of a chain was substandard. If the proposal is to allow pharmacy premises matters to be dealt with as a matter of discipline, and where a single failure

leads only to the potential for removal of only the one pharmacy (save for the gravest of circumstances), then PSNC would support that.

**Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?**

The current pause and reconsideration of the grading of pharmacy reports is welcome, because pharmacy owners are naturally concerned by the negative perception that can be created from an inspection report that is misunderstood by the public. These concerns must be adequately addressed and an appropriate summary report template which can be easily understood by the public must be developed before any consideration is given to publicising the reports of inspections.

PSNC also notes that the frequency of visits made by the GPhC is low, and there is a considerable risk at present, that a report which may be correct today, might remain in place for several years until the next inspection. Where an adverse finding affects a pharmacy inspection report, the pharmacy owner must not only have the opportunity to challenge the report itself, but must have the ability to remedy any failings, and request an updated inspection report to reflect the improvements that have taken place.

**Question 14: Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?**

Yes. The oversight by the Privy Council of the Rules that would set out the information that may be requested provides reassurance about the process, but it would be helpful that the Rules should provide clarity about what level of detail is required, and the frequency of requests.

**Question 15: An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree our assessment? If not, please provide details and estimates of any impacts and costs that you consider are not relevant or, alternatively, have not been taken into account.**

No comment.

**Question 16: Do you consider there are any additional significant impacts or benefits on any sector involved that we have not yet identified? Please provide details and estimates.**

No comment.

**Question 17: As part of preparing this IA we have asked business representatives whether, if the new defence were introduced, it would have a downward impact on employee cost pressures (for instance, any reduction in the risk of being prosecuted could slightly reduce legal or insurance costs). No significant cost impacts have so far been identified. Are there specific impacts on small and micro-businesses that we need to take into account?**

No comment.

**Question 18: At this stage, we do not consider it is feasible to estimate a "typical" cost of prosecutions for dispensing errors on individual professionals or pharmacy businesses because of the small numbers involved over the last decade. Do you agree with this? If not, do you have any relevant information which we can consider?**

Yes.

**Question 19: We have provided an estimate of the magnitude of the cost and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general Rebalancing Medicines Legislation and**

**Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999 45 assumptions – summarised in Annex B of the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic? If not, what assumptions should we use? Please provide an estimate of the cost of such assumption.**

No comment

**Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.**

No comment

**Question 21: Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.**

No comment

**Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules-based approach compared to an outcome based system. Please say (i) what assumptions we should use (ii) identify the impacts and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.**

No comment

**Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?**

No